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**Description**

This invention relates to a liquid food effective for improving constipation. Particularly, this invention relates to a liquid food effective for improving constipation, which being superior in taste, and pleasant to the palate.

Recently the role of fibrous materials contained in food, that is so called edible fibers or dietary fibers, in dietary life has become more and more important. There have already been many studies regarding the physiological importance of taking in edible fiber. For example, one of the result that Burkit reported after studying the dietary life of African natives, is that those people who had diets that included lot of edible fiber had lower rates of appendicitis, diverticulum diseases, cardiovascular diseases and colic cancer than Westerners with low fiber diets. Also, Ebihara et al, as a result of experiments using edible fibers and wheat bran, confirmed that edible fibers shorten retention time of food in the body, and increases the amount and water content of feces.

These results of these studies hold interest particularly from the aspect of curing and preventing constipation, and recently it is being done to treat a material abundant in edible fibers such as bran or germ for easy eating or blend into a conventional foods. Further, the use of edible fiber together with other physiologically useful substances to enhance their effects has also been tried. For example Japanese Patent Laid Open No.59-173062 offers a health food for improving constipation which consists of edible fiber and a proliferation accelerating factor for bifidobacterium (eg. lactulose).

However, as edible fibers are generally difficult to stably suspend in water, such a conventional kinds of foodstuff were limited to foods in a solid state, and there has been no liquid food or beverage having incorporated edible fiber in order to improve constipation. And also, the above mentioned conventional food containing edible fiber can easily have their taste and texture corrupted by the addition of edible fiber, therefore, if taste should be taken into consideration as an important factor, there is the problem that sufficient amounts of edible fiber cannot be incorporated therein. Further, the fact that liquid food cannot be produced makes it difficult to increase the variety of presentable foods containing edible fiber, making it hard to meet consumers' diversified tastes.

In order to expect any significant effect, in many cases fairly large amounts of edible fiber should be taken, but this is often accompanied by side effects such as diarrhoea, flatulence, abdominal inflation, celiacgia, etc. Therefore, it is not recommendable to take in too much edible fiber at one time.

This invention relates to providing a novel liquid food having superior taste and texture that is easy to ingest, and which in small amounts, can impart remarkable effects in improving constipation.

The present invention provides a liquid food for relieving constipation characterised in that it contains

(a) a water soluble polysaccharide having a molecular weight of 1500 to 18000 which is obtained by polymerising glucose or maltose in a molten state using edible carboxylic acid as a catalyst and crosslinking agent (Polydextrose<sup>R</sup>); and

(b) a water soluble oligosaccharide product, other than a disaccharide, which is substantially non-digestible by human digestive enzymes but is easily fermentable by intestinal bacteria; the ratio of (a) to (b) being from 1:10 to 20:1 by weight.

An example of a liquid food provided by the present invention comprises, as main components for improving constipation, Polydextrose<sup>R</sup> and raffinose family oligosaccharides which are made from soybean and are hard to digest and easy to ferment. Another example of a liquid food provided by the present invention comprises, as main components for improving constipation, Polydextrose<sup>R</sup> and galactose series oligosaccharides which are made from lactose and are hard to digest and easy to ferment.

In a liquid food of the present invention, both Polydextrose<sup>R</sup> and oligosaccharides are completely water soluble, have no solid substance and have good texture. Although each component has an effect for improving constipation, much greater effects are shown when both components are used together.

In the present invention, liquid food refers not only to a food which is fluid in its ordinary state but also to a food having a potentially fluid character which can be easily converted to a liquid food such as pudding, jelly or ice cream when agitated or heated. In the present invention, a food also includes a beverage.

Polydextrose<sup>R</sup> means water soluble polysaccharide having a molecular weight of 1500-18000 which is obtained by polymerizing glucose or maltose in a molten state using edible carboxylic acid, eg. citric acid, as a catalyst and crosslinking agent. Apart from abovementioned polysaccharide, there are those which are obtained by reacting polyol such as sorbitol in order to decrease viscosity and to improve color and taste, a method for making such products is described in USP 3,766,185. The molecular chain of the polysaccharide is highly branched and hard to digest and the calorific content of it as a food is as low as 1 calorie per gram, h retofore it having been used as a low cal ry saccharic foodstuff. According to the inventors'

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confirmation, polydextrose, being different from oligosaccharides which are another component of the present invention that are hard to digest and easy to ferment, is difficult to be utilized even by intestinal bacteria. The substance is being sold by Pfizer Inc. under the trade name of "Polydextrose".

On the other hand, oligosaccharides, which are hard to digest and easy to ferment, are difficult for digesting enzymes secreted from the human digestive tract to digest but they are easily utilized by intestinal bacteria. For example, the oligosaccharides of the invention are such fermentable substances that when mixed with four times diluted fresh human feces and kept in an anaerobic condition, more than 80 % would be diminished. In ordinary terms oligosaccharides include disaccharides, however, as most disaccharides are easy to digest and those disaccharides that are not easy to digest do not show significant effect when used together with polydextrose, disaccharides are excluded from the oligosaccharides of the present invention.

Especially preferable oligosaccharides for the present invention are those which can be utilized by bifidobacteria having a regulatory effect on intestine. The oligosaccharides exemplified are: such raffinose family oligosaccharides which are made from soybean described in Japanese Patent Laid Open No.59-179064, galactose series oligosaccharides which are made from lactose described in Japanese Patent Publication No.58-20266, fructooligosaccharides described in Japanese Patent Publication No.59-53834, product of decomposition of Konjak mannan described in Japanese Patent Laid Open No.58-212780, levan (beta-2,6-fructan) described in Japanese Patent Laid Open No.57-18982, galactose series oligosaccharides which are made from lactose described in Japanese Patent Laid Open No.58-99497, partially hydrolyzed chitin described in Japanese Patent Laid Open No.59-53835, lactosucrose described in Japanese Patent Publication 59-53835.

Mixing ratio of Polydextrose<sup>R</sup> and oligosaccharides which are hard to digest and easy to ferment is suitably 1:10 - 20:1. A liquid food of the present invention can be incorporated, apart from Polydextrose<sup>R</sup> and oligosaccharides which are hard to digest and easy to ferment, with other oligosaccharides which are hard to digest and are water soluble seasonings, flavors, and other appropriate materials in so far as they do not adversely affect the achievement of the present invention. Especially, lactobacilli, streptococci, bifidobacteria or fermented milk containing them which have a regulatory effect on intestine preferable as subcomponents, since they are superior in view of their ingestive effect in the liquid food of the present invention.

In the present invention, both Polydextrose<sup>R</sup> and oligosaccharides are also effective in improving constipation. Although the mechanisms which affect said improvement are not clear, it is deemed that they both work in different ways due to their different fermenting abilities in the intestines, and when they are used together, significant effects much more superior to their being used alone can be shown. Since both materials are completely water soluble, they are suitable for making a liquid food having no solid residue and good texture.

Since the liquid food of the present invention achieves the object of improving constipation through the use of water soluble Polydextrose<sup>R</sup> and oligosaccharides, it has a taste and texture superior to those of conventional health foods which contain solid edible fibers. Moreover, since it is a stable liquid, it can be made in a variety of forms such as a beverage, fermented milk, jelly, ice cream etc., and can meet diversified consumers' tastes.

#### Example

In order to explain the invention in more detail, dosage tests and manufacturing examples are shown below. In each example the Polydextrose<sup>R</sup> used was manufactured by Pfizer Inc.

#### Dosage tests:

The effects on constipation of Polydextrose<sup>R</sup> and raffinose family oligosaccharides which were made from soybean were inspected by dosing them solely respectively or all together at the same time to subjects comprising an adult male and nine adult females complaining of constipation or a touch of constipation. The raffinose family oligosaccharides used were prepared by a method described in Japanese Patent Laid den No.59-179064, where soybean whey was treated with calcium hydroxide.

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( amount of dose )

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test group 1:	polydextrose <sup>R</sup>	10 g/day
test group 2:	raffinose family oligosaccharides	3 g/day
test group 3:	polydextrose and raffinose family oligosaccharides	5 g/day 3 g/day

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( duration of dose )

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Each test group was dosed for 2 weeks. In order to avoid any influences from a preceeding test, a non dosage term of one week was set between each test group. Testing order for the groups was randomly changed according to subjects.

( method of inspecting the results )

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All subjects were requested to fill out and respond to a questionnaire containing the following items everyday before, in the midst of, and after each dosage:

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1. Whether defecation had occurred;
2. Ease in defecating;
3. Amount of stool ( great, normal, little );
4. Nature of stool ( hard, medium, soft, diarrhetic );
5. Feeling after defecation ( feeling of relief or not );

( method for analyzing the results )

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The results were scored as follows:

1. Frequency of defecation;  
frequency of defecation / test term (14 days)
2. Ease of defecation;  
frequency of easy defecation during test term / frequency of defecation during test term
3. Amount of stool;

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Points of 3, 2, and 1 were allotted for the amount ie. great, normal, little, respectively and totaled through the duration of the dosage.

4. Hardness;

Points of 1, 2, 3, and 4, were allotted for the hardness ie. hard, medium, soft, and diarrhetic, respectively. Total points were divided by the frequency of defecation with the quotient as the resulting score

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5. Degree of relief;

frequency the subject felt sense of relief after defecation / frequency of the defecation made during the test

The resulting score are shown in Table 1 and Table 2 hereinbelow.

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Table 1 shows the results of effect for improving constipation according to each test group, where a circle expresses that four or more than four items out of the five items tested had improved compared to before the dosage. Table 2 shows the items which were judged as showing significantly increased scores according to "Student's t-test" for each item comparing the state before dosage and the result of the test.

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Tabl 1

	<u>subject</u>	<u>test group</u>		
		<u>1</u>	<u>2</u>	<u>3</u>
5	A	○	○	○
10	B			○
	C	○		○
15	D		○	
	E			
20	F			
	G	○	○	○
25	H		○	○
	I	○		
30	J			○
<hr/>				
35	number of subjects scoring as effective	4	4	6

Table 2

<u>test group</u>	<u>items showing significantly increased score</u>
45 1	none
2	frequency of defecation and amount.
50 3	frequency of defecation, amount, ease and hardness.

In general, a condition where constipation is cured can be seen as a condition where frequency of defecation is increased, feces becomes soft and easy to defect, and where the subject feels relieved after defecation. Hence, it cannot be determined that constipation is cured after seeing an improvement in only one item. Therefore the indispensable requirements for judging whether constipation has been cured are as follows:

- (1) With respect to on item, the score increases significantly through all subjects;

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(2) Through all subjects, a significant increase in score can be seen in as many items as possible;

(3) With respect to an individual subject, the scores increase in almost all items.

In determining the above results based on the three items above, a curing effect on constipation cannot be seen at all when only Polydextrose<sup>R</sup> was dosed, a slightly effect can be seen with oligosaccharides alone, and can be strongly recognized when Polydextrose<sup>R</sup> and oligosaccharides are used together.

#### Manufacturing examples:

##### (Example 1)

To 10 liters of apple juice, 500 g of Polydextrose<sup>R</sup> and 300 g of raffinose family oligosaccharides which were made from soybean as used in the above test were added and sterilized by heating to 100 °C for 30 minutes. The thus obtained fruit juice was clear, having good taste and flavor with no odd sensations to the palate.

##### (Example 2)

To 100 parts by weight of commercial fermented milk product containing bifidobacterium (produced by KK Yakult Honsha and sold under the trade name of "MIL-MIL"), 5 parts by weight of Polydextrose<sup>R</sup> and 3 parts by weight of galactose series oligosaccharides which were produced from lactose according to a method described in Japanese Patent Publication No.58-20266 were added in an aseptic condition. The beverage obtained was not inferior to the fermented milk used as a raw material with respect to taste and pleasant feeling to the palate.

##### (Example 3)

To 400 g of Polydextrose<sup>R</sup> 240 g of raffinose family oligosaccharides as used in the previous example, 24 g of citric acid and 670 g of sucrose, water was added to make 10 liters of liquid, and sterilized by heating to 100 °C, for 30 minutes. To the resulting mixture was added 1 liter of fermented milk which was previously prepared by culturing Lactobacillus casei on a culture medium of 10 % skimmed milk, and having  $1 \times 10^9$ /ml of viable cells. The lactobacilli-containing beverage thus obtained had good taste and flavor and a pleasant feeling to the palate.

##### (Example 4)

Using the following recipe, ice cream was made according to a conventional method:

raw cream (45% formulated)	1000 g
milk	450
Polydextrose <sup>R</sup>	75
55% fructo-oligosaccharides syrup*	118
sugar	100
egg yolks	200
flavor	a few drops

\* produced by Meiji Seika KK, Bx 73.5

The product thus obtained was not any different from conventional ice cream in pleasant feeling to the palate.

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(Example 5)

With the following recipe, coffee jelly was made according to a conventional method.

instant coffee powder	25 g
Polydextrose <sup>R</sup>	100
50% galactose series oligosaccharides (the remaining 50% being unreacted materials and by-products composed mainly of galactose, glucose, lactose)	172
Sugar	75
water	1000
gelatine	25
* made by a method according to Japanese Patent Laid Open No.58-20266, Bx 70	

509  
Jg  
not polys.

The product thus obtained was not any different in texture from conventional coffee jelly.

#### Claims

1. A liquid food for relieving constipation characterised in that it contains
  - (a) a water soluble polysaccharide having a molecular weight of 1500 to 18000 which is obtained by polymerising glucose or maltose in a molten state using an edible carboxylic acid as a catalyst and crosslinking agent (Polydextrose<sup>R</sup>); and
  - (b) a water soluble oligosaccharide product, other than a disaccharide, which is substantially non-digestible by human digestive enzymes but is easily fermentable by intestinal bacteria; the ratio of (a) to (b) being from 1:10 to 20:1 by weight.
2. A composition according to claim 1, characterised in that the oligosaccharide product (b) comprises raffinose family oligosaccharides derived from soy bean.
3. A composition according to claim 1 characterised in that the oligosaccharide product (b) comprises galactose series oligosaccharides derived from lactose by the action of  $\beta$ -galactosidase.
4. A composition according to claim 1 characterised in that the oligosaccharide product (b) is selected from:
  - (i) raffinose oligosaccharides selected from raffinose and stachyose;
  - (ii) galactose-series oligosaccharides of the formula  $\text{Gal}-(\text{Gal})_m\text{Glc}$ , where  $m = 1, 2, 3$  or  $4$  or  $\text{Gal}-(\beta-1,6)\text{-Glc}-(\beta-1,4)\text{-Gal}$ ;
  - (iii) fructo-oligosaccharide of the formula  $\text{Fru}-(\text{Fru})_m\text{-Glc}$ , where  $m = 1, 2, 3$  or  $4$  or  $\text{Fru}-(\text{Fru})_n\text{-Glc-Fru}$ , where  $n = 0$  or  $1$ ;
  - (iv) decomposition product of Konjak mannan, being an oligosaccharide comprising glucose and mannose;
  - (v) levan ( $\beta$ -2,6-fructan);
  - (vi) partially hydrolysed chitin of the formula  $\text{Gal}-(\text{GlcNAc})_m\text{-Glc}$ , where  $m = 1, 2, 3$  or  $4$ ; and
  - (vii) lactosucrose of the formula  $\text{Gal-Glc-Fru}$ ; where Gal = galactose moiety; Glc = glucose moiety; Fru = fructose moiety; GlcNAc = N-acetylglucosamine moiety.
5. A composition according to any of claims 1 to 4 which is fluid in its ordinary state or has a potentially fluid character convertible to a liquid on being agitated or heated.
6. A composition according to claim 5 in the form of a beverage.

#### Patentansprüche

1. Flüssignahrung zu Linderung von Verstopfung, dadurch gekennzeichnet, dass sie enthält
  - (a) ein wasserlösliches Polysaccharid mit einem Molekulargewicht von 1500 bis 18000, das erhalten wird durch Polymerisation von Glucose oder Maltose in geschmolzenem Zustand unter Verwendung einer essbaren Carbonsäure als Katalysator und Vernetzungsmittel (Polydextrose<sup>R</sup>); und



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(b) in wasserlösliches Oligosaccharidprodukt, verschieden von einem Disaccharid, welches im wesentlichen unverdaulich für menschliche Verdauungsenzyme, jedoch leicht fermentierbar durch Intestinalbakterien ist; wobei das Verhältnis von (a) zu (b) 1:10 bis 20:1 Gew.-Teile beträgt.

2. Zusammensetzung gemäss Anspruch 1, dadurch gekennzeichnet, dass das Oligosaccharid-Produkt (b) Oligosaccharide aus der Raffinose-Familie enthält, die von der Sojabohne stammen.
3. Zusammensetzung gemäss Anspruch 1, dadurch gekennzeichnet, dass das Oligosaccharid-Produkt (b) Oligosaccharide aus der Galactosereihe umfasst, abgeleitet von Lactose durch die Wirkung von  $\beta$ -Galactosidase.
4. Zusammensetzung gemäss Anspruch 1, dadurch gekennzeichnet, dass das Oligosaccharid-Produkt (b) ausgewählt ist aus:
  - (i) Raffinose-Oligosacchariden, ausgewählt aus Raffinose und Stachyose;
  - (ii) Oligosacchariden aus der Galactosereihe der Formel  $\text{Gal}-(\text{Gal})_m\text{-Glc}$ , worin  $m = 1, 2, 3$  oder  $4$ , oder  $\text{Gal}-(\beta-1,6)\text{-Glc}-(\beta-1,4)\text{-Gal}$ ;
  - (iii) Fructooligosacchariden der Formel  $\text{Fru}-(\text{Fru})_m\text{-Glc}$ , wobei  $m = 1, 2, 3$  oder  $4$ , oder  $\text{Fru}-(\text{Fru})_n\text{-Glc-Fru}$ , wobei  $n = 0$  oder  $1$ ;
  - (iv) Zersetzungsprodukten von Konjak-Mannan, das ein Oligosaccharid ist, das Glucose und Mannose umfasst;
  - (v) Levan ( $\beta$ -2,6-Fructan);
  - (vi) partiell hydrolysiertem Chitin der Formel  $\text{Gal}-(\text{GlcNAc})_m\text{-Glc}$ , wobei  $m = 1, 2, 3$  oder  $4$ ; und
  - (vii) Lactosucrose der Formel  $\text{Gal-Glc-Fru}$ , worin  $\text{Gal} = \text{Galactoseeinheit}$ ;  $\text{Glc} = \text{Glucoseeinheit}$ ;  $\text{Fru} = \text{Fructoseeinheit}$ ; und  $\text{GlcNAc} = \text{N-Acetylglucosamin-Einheit}$ .
5. Zusammensetzung gemäss einem der Ansprüche 1 bis 4, die in ihrem Normalzustand flüssig ist oder einen potentiell flüssigen Charakter hat, d.h. in eine Flüssigkeit umwandelbar ist, wenn sie gerührt oder erwärmt wird.
6. Zusammensetzung gemäss Anspruch 5 in Form eines Getränkes.

## Revendications

1. Un aliment liquide pour atténuer la constipation, caractérisé en ce qu'il contient
  - (a) un polysaccharide hydrosoluble ayant un poids moléculaire de 1500 à 18 000, qui est obtenu en polymérisant du glucose ou du maltose à l'état fondu en utilisant un acide carboxylique comestible comme catalyseur et un agent de réticulation (Polydextrose®); et
  - (b) un produit oligosaccharide hydrosoluble, autre qu'un disaccharide, qui est sensiblement non digestible par les enzymes digestives humaines, mais qui est facilement fermentescible par les bactéries intestinales;
 le rapport de (a) à (b) étant de 1:10 à 20:1 en poids.
2. Une composition selon la revendication 1, caractérisée en ce que le produit oligosaccharide (b) comprend des oligosaccharides de la famille du raffinose dérivés de soja.
3. Une composition selon la revendication 1, caractérisée en ce que le produit oligosaccharide (b) comprend des oligosaccharides de la série du galactose dérivés de lactose par l'action d'une  $\beta$ -galactosidase.
4. Une composition selon la revendication 1, caractérisée en ce que le produit oligosaccharide (b) est choisi parmi :
  - (i) des oligosaccharides de la famille du raffinose choisis parmi le raffinose et le stachyose;
  - (ii) des oligosaccharides de la série du galactose de la formule  $\text{Gal}-(\text{Gal})_m\text{-Glc}$ , où  $m = 1, 2, 3$  ou  $4$ , ou  $\text{Gal}-(\beta-1,6)\text{-Glc}-(\beta-1,4)\text{-Gal}$ ;
  - (iii) un fructo-oligosaccharide de la formule  $\text{Fru}-(\text{Fru})_m\text{-Glc}$ , où  $m = 1, 2, 3$  ou  $4$ , ou  $\text{Fru}-(\text{Fru})_n\text{-Glc-Fru}$ , où  $n = 0$  ou  $1$ ;
  - (iv) un produit de décomposition de mannane de konjak, qui est un oligosaccharide comprenant du glucose et du mannose;

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(v) le lévane ( $\beta$ -2,6-fructane) ;

(vi) une chitine partiellement hydrolysé de la formule  $\text{Gal}-(\text{GlcNAc})_m\text{-Glc}$ , où  $m = 1, 2, 3$  ou  $4$  ; et

(vii) un lactosaccharos de la formule  $\text{Gal-Glc-Fru}$  ; où Gal = motif de galactose ; Glc = motif de glucose ; Fru = motif de fructose ; GlcNAc = motif de N-acétylglucosamine.

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5. Une composition selon l'une quelconque des revendications 1 à 4, qui est fluide dans son état normal ou qui a un caractère potentiellement fluide transformable en un liquide par agitation ou chauffage.

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6. Une composition selon la revendication 5, sous la forme d'une boisson.

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